DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 6, 2015

EUROSETS s.r.l.
% Mario Gennari
Official Correspondent, Gemar s.r.l.
Via G. Puccini, 1
Medolla, Modena, IT I-43036

Re: K141492
Trade/Device Name: Advanced Membrane Gas Exchange PMP Sterile (A.M.G. PMP Sterile)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: December 4, 2014
Received: January 14, 2015

Dear Mario Gennari,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141492

Device Name
Advanced Membrane Gas Exchange PMP (A.M.G. PMP STERILE)

Indications for Use *(Describe)*
The Advanced Membrane Gas Exchange PMP STERILE (A.M.G. PMP STERILE) is intended for use in adult Surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours.

The Advanced Membrane Gas Exchange PMP STERILE (A.M.G. PMP STERILE) for extracorporeal circulation is a microporous hollow-fiber oxygenator with an integral heat exchanger used to perform cardiopulmonary bypass. It includes a detachable 4.5 liter blood reservoir.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY, AS REQUIRED BY 21 CFR 807.92

Submitter's Name	Eurosets s.r.l.
Address	Strada Statale 12, n°143 41036 Medolla (MO) Italy
Establishment Registration Number	3003752502
Summary Preparation Date	Feruary 05, 2015
Contact Person **Telephone Number** **Fax Number**	Dr. Katia Vescovini, Regulatory Affairs Manager 0039 0535660334 0039 0535 51248
Name of the Device	Advanced Membrane Gas Exchange PMP STERILE (A.M.G. PMP STERILE)
Name of the Oxygenating module	A.M.G. MODULE PMP STERILE A.M.G. MODULE PMP NO T.P. STERILE
Name of the Cardiotomy reservoir	VCR 4500 PMP STERILE
Common name of the device	Advanced Membrane Gas Exchange and Accessories A.M.G. PMP STERILE
Common name of the Oxygenating module	A.M.G. MODULE PMP STERILE A.M.G. MODULE PMP NO T.P. STERILE
Common name of the Cardiotomy reservoir	Venous Cardiotomy Reservoir 4500 PMP STERILE
Classification Name	Cardiopulmunary device Classification Name: Advanced membrane gas exchange Device Class: II Product Code: DTZ Regulation Number: 21 CFR §870.4350
Performance Standards	No performance standards applicable to Advanced Membrane Gas Exchange PMP STERILE (A.M.G. PMP STERILE) have been established by the FDA

DESCRIPTION:	The Advanced Membrane Gas Exchange and accessories PMP STERILE (A.M.G. PMP STERILE) is a microporous hollow-fiber oxygenator with an integral heat exchanger, used to perform cardiopulmonary bypass or surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. It includes a detachable 4.5 liter blood reservoir. The A.M.G. PMP STERILE is equipped with polymethyl pentene fibres, more hydrophobic than the polyethylene used for the predicate device and so considered a more reliable barrier between the blood pathway and gas pathway of the oxygenator. The A.M.G. PMP STERILE is provided in different configurations: - microporous hollow-fiber oxygenator with temperature probe and pre-connected venous cardiotomy reservoir ("A.M.G. PMP STERILE"), - microporous hollow-fiber oxygenator with temperature probe and without pre-connected venous cardiotomy reservoir ("A.M.G. MODULE PMP STERILE"), - microporous hollow-fiber oxygenator without temperature probe and without pre-connected venous cardiotomy reservoir ("A.M.G. MODULE PMP NO TP STERILE") , - Venous Cardiotomy Reservoir 4500 PMP ("VCR 4500 PMP STERILE"). The device is used to temporarily substitute the functions of the lung as it supplies oxygen and removes carbon dioxide from the blood. The device can be use with adult patients.
Indications for Use	The Advanced Membrane Gas Exchange PMP STERILE (A.M.G. PMP STERILE) is intended for use in adult Surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to 6 hours. The Advanced Membrane Gas Exchange PMP STERILE (A.M.G. PMP STERILE) for extracorporeal circulation is a microporous hollow-fiber oxygenator with an integral heat exchanger used to perform cardiopulmonary bypass. It includes a detachable 4.5 liter blood reservoir.
Identification of Predicate Device	Proprietary Name: AMG Classification Name: 21 CFR 870.4350, Oxygenator, Cardiopulmonary Bypass Registered Establishment Name: Eurosets srl Strada Statale 12, n. 143 41036 Medolla (MO) Italy

	Registered Establishment Number: 3003752502 Owner/Operator: Eurosets srl Establishment Operations: Manufacturer 510 (k): K102109 Device Name: A.M.G. advanced membrane gas exchange and accessories Applicant: Eurosets srl Please note that regarding the polymethyl pentene fibres used by the A.M.G. PMP STERILE, Eurosets will refer to the following predicate device: Proprietary Name: MEDOS HILITE 7000 & 7000 LT Hollow Fiber Oxygenator Classification Name: 21 CFR 870.4350, Oxygenator, Cardiopulmonary Bypass Registered Establishment Name: GISH BIOMEDICAL, INC. Registered Establishment Number: 3002845651 Owner/Operator: GISH BIOMEDICAL, INC. Owner/Operator Number: 3002845651 Establishment Operations: Manufacturer 510 (k): K082403 Device Name: 7000 LT Hollow Fiber Oxygenator (K082403) Applicant: GISH BIOMEDICAL, INC.
Common name of the predicate device for principles of operatations	A.M.G. advanced membrane gas exchange and accessories
Classification Name of the device	Oxygenator, Cardiopulmonary Bypass Device Class: II Product Code: DTZ Regulation Number: 21 CFR §870.4350
Classification Name of the Oxygenating module	Oxygenator cardiopulmonary bypass Cardiovascular Device Class: II Product Code: DTZ Regulation Number: 21 CFR §870.4350
Classification Name of the Cardiotomy reservoir	Hard shell Venous/cardiotomy reservoir Cardiovascular Device Class: II Product Code: DTZ Regulation Number: 21 CER §870.4350
Applicant name and address:	Eurosets s.r.l. Strada Statale 12, n°143 41036 Medolla (MO) Italy MEDOS MEDIZINTECHNIK AG Obere Steinfurt 8-10

	Stolberg, GERMANY 52222
Comparison of Technological Characteristics	In vitro bench testing was performed to support a determination of substantial equivalence (refer to performance testing below) between the new Advanced Membrane Gas Exchange PMP STERILE (A.M.G. PMP STERILE) and the predicate. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use and performs comparably to the existing predicate devices.
Performance Testing (non-clinical)	In vitro bench tests were carried out to demonstrate equivalence, according to the requirements of FDAs document "Guidance for Cardiopulmunary Bypass Oxygenators 510(k) Submission", issued on November 13, 2000, the ISO 7199:2009 and of the EN 12022:1998 "Blood-gas exchangers". The following areas have been tested and/or evaluated: - Gas Transfer and Pressure Drop, - Fiber Hydrophilization, - Cracking test external body, - Coating Uniformity, - Plasma hemoglobin concentration, - Heat exchanger Efficiency and Filling Volume, - Seal Connection, - Structural and Mechanical Integrity, - Bioburden tests, - Sterility tests, - LAL-test, - Validation of the EtO Sterilization process, - Sterility tests, - Packaging evaluation, - Labelling evaluation, - EtO Residual, according to EN ISO 10993-7, - Biocompatibility, according to ISO 10993 series requirements. The results from these performance evaluations demonstrated that the AMG PMP STERILE met the acceptarfce criteria defined in the product specification and performed comparably to the predicate device.
SUBSTANTIAL EQUIVALENCE:	The A.M.G PMP STERILE are identical to the predicate device in terms of intended use, indications for use and surgical technique. Based on the safety and performance testing, technological characteristics and the indications for use for the device, the proposed A.M.G PMP STERILE has been demonstrated to be appropriate for its intended use and is considered substantially equivalent to the previously cleared A.M.G. advanced membrane gas exchange and accessories (K102109).